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PATENT & TRADEMARK

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Allen

Art Unit  
1635

For: MUSCLE DIRECTED GENE TRANSFER BY USE OF  
RECOMBINANT AAV-1 AND AAV-6 VIRIONS

Examiner: Brian A. Whiteman

TO THE COMMISSIONER FOR PATENTS:

- ☒ Copies of listed documents are enclosed. (37 CFR § 1.98(a))
- ☐ Copies of listed U.S. patent documents are omitted because this application was filed after June 30, 2003 and is, thus, subject to image file wrapper processing. Copies of listed foreign patent documents and non-patent literature are enclosed.
- ☐ Copies of the documents listed on sheet(s) \_\_\_\_\_ of Form PTO-1449 (or equivalent) are omitted because (1) they are already of record in U.S. Patent Application No. \_\_\_\_\_, filed \_\_\_\_\_, on which this application relies for an earlier filing date under 35 U.S.C. § 120; and (2) any information disclosure statement filed in the prosecution of Application No. \_\_\_\_\_, complies with 37 CFR §§ 1.98(a) through (c). (37 C.F.R. § 1.98(d))

- SaltLake-227107.1 0051271-00033

3. This information disclosure statement is being submitted (check box a., b., or c.):
- a. ☐ Within three months of the filing date of a national application or entry of the national stage in an international application; or before the mailing of a first Office action on the merits; or before the mailing of a first Office action after the filing of a request for continued examination under 37 CFR 1.114. (No statement under 37 CFR 1.97(e) is required.); or
  - b. ☒ After the period set forth in paragraph 3a, but before the mailing date of either a final action, a notice of allowance, or an action that otherwise closes prosecution in the application. (Check box i. or ii.)
    - i. ☒ A \$180.00 information disclosure statement submission fee set forth in 37 CFR 1.17(p) is enclosed, or
    - ii. ☐ A statement specified by 37 CFR 1.97(e) is set forth below; or
  - c. ☐ After the mailing date of a final action or notice of allowance and on or before payment of the issue fee. A statement specified by 37 CFR 1.97(e) is set forth below. Enclosed is a \$180.00 information disclosure statement processing fee set forth in 37 CFR 1.17(p).
4. If a statement specified by 37 CFR 1.97(e) is required, the attorney or agent signing below hereby states that:
- ☐ each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement; or
  - ☐ no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement.

5. ☐ A concise explanation of the relevance of each document not in the English language and/or selected documents in the English language is set forth below.

DATED this \_\_\_\_ day of May, 2004.

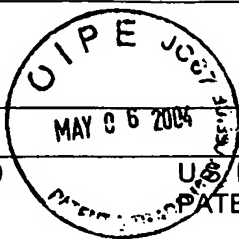
Respectfully submitted,



Mara K. Featherstone  
Registration No. 50,390

STOEL RIVES LLP  
One Utah Center  
201 South Main Street, Suite 1100  
Salt Lake City, UT 84111  
Telephone: (801) 578-6932  
Facsimile: (801) 578-6999

**CUSTOMER NO. 35735**



## PTO-FORM 1449

Sheet 1 of 1

FORM PTO-1449  
(REV. 7-80)U.S. DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICEATTY. DOCKET NO.  
51271/33 US  
(Avigen Ref. 1023.US)APPLICATION NO.  
10/056,788Title: MUSCLE DIRECTED GENE TRANSFER BY USE OF  
RECOMBINANT AAV-1 AND AAV-6 VIRIONS

Art Unit: 1635

APPLICANT - Allen

FILING DATE-  
January 23, 2002EXAMINER  
Brian A. Whiteman

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	1	6,221,349	Apr. 24, 2001	Couto et al.	A61K	35/00	Jul. 30, 1999

## OTHER DOCUMENTS (Including Author, Title, Date, Relevant Pages, Place of Publication, etc.)

2	Flotte et al., Clinical Protocol "Phase I Trial of Intramuscular Injection of a Recombinant Adeno-Associated Virus Alpha 1-Antitrypsin (rAAV2-CB-hAAT) Gene Vector to AAT-Deficient Adults, <i>Human Gene Therapy</i> 14:93-128 (2004).
3	Song et al., Recombinant adeno-associated virus-mediated alpha-1 antitrypsin gene therapy prevents type I diabetes in NOD mice, <i>Gene Therapy</i> (2004).
4	Mochizuki et al., Long-term correction of hyperphenylalaninemia by AAV-mediated gene transfer leads to behavioral recovery in phenylketonuria mice, <i>Gene Therapy</i> (2004).
5	Galeano et al., Adeno-associated viral vector-mediated human vascular endothelial growth factor gene transfer stimulates angiogenesis and wound healing in the genetically diabetic mouse, <i>Diabetologia</i> (2003).
6	Tsai et al., Gene treatment of cerebral stroke by rAAV vector delivering IL-1ra in a rat model, <i>Molecular Neuroscience, NeuroReport</i> (2003).
7	Skorupa et al., Sustained Production of $\beta$ -Glucuronidase from Localized Sites after AAV Vector Gene Transfer Results in Widespread Distribution of Enzyme and Reversal of Lysosomal Storage Lesions in a Large Volume of Brain in Mucopolysaccharidosis VII Mice, <i>Experimental Neurology</i> (1999).

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformation with MPEP609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

CUSTOMER NO. 35735

**TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT**  
**(Under 37 CFR 1.97(b) or 1.97(c))**

Docket No.  
51271/33

In Re Application Of: **Allen**

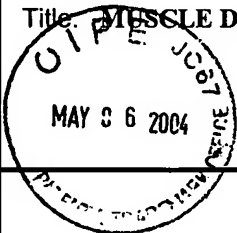
Serial No.  
10/056,788

Filing Date  
January 23, 2002

Examiner  
Brian A. Whiteman

Group Art Unit  
1635

Title: **MUSCLE DIRECTED GENE TRANSFER BY USE OF RECOMBINANT AAV-1 AND AAV-6 VIRIONS**



Address to:  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**37 CFR 1.97(b)**

1. ☐ The Information Disclosure Statement submitted herewith is being filed within three months of the filing of a national application other than a continued prosecution application under 37 CFR 1.53(d); within three months of the date of entry of the national stage as set forth in 37 CFR 1.491 in an international application; before the mailing of a first Office Action on the merits, or before the mailing of a first Office Action after the filing of a request for continued examination under 37 CFR 1.114.

**37 CFR 1.97(c)**

2. ☒ The Information Disclosure Statement submitted herewith is being filed after the period specified in 37 CFR 1.97(b), provided that the Information Disclosure Statement is filed before the mailing date of a Final Action under 37 CFR 1.113, a Notice of Allowance under 37 CFR 1.311, or an Action that otherwise closes prosecution in the application, and is accompanied by one of:

☐ the statement specified in 37 CFR 1.97(e);

**OR**

☒ the fee set forth in 37 CFR 1.17(p).

<b>TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT</b> (Under 37 CFR 1.97(b) or 1.97(c))			Docket No. 51271/33
In Re Application:    Allen			
Serial No. 10/056,788	Filing Date January 23, 2002	Examiner Brian A. Whiteman	Group Art Unit 1635
<b>MUSCLE DIRECTED GENE TRANSFER BY USE OF RECOMBINANT AAV-1 AND AAV-6</b>			
<div style="text-align: center;"> <b>Payment of Fee</b>          (Only complete if Applicant elects to pay the fee set forth in 37 CFR 1.17(p))       </div> <div style="margin-top: 10px;"> <input type="checkbox"/> A check in the amount of _____ is attached.  <input checked="" type="checkbox"/> The Director is hereby authorized to charge and credit Deposit Account No.    <b>50-2375</b>             as described below.         <div style="display: flex; justify-content: space-between; margin-top: 5px;"> <div> <input type="checkbox"/> Charge the amount of _____  <input checked="" type="checkbox"/> Credit any overpayment.  <input checked="" type="checkbox"/> Charge any additional fee required.           </div> <div> <input checked="" type="checkbox"/> USPTO Credit Card Form 2038 - \$180           </div> </div> </div> <div style="display: flex; justify-content: space-between; margin-top: 20px;"> <div style="width: 45%;"> <p style="text-align: center;"><b>Certificate of Transmission by Facsimile*</b></p> <div style="border: 1px solid black; padding: 5px; margin-bottom: 5px;">           I certify that this document and authorization to charge deposit account is being facsimile transmitted to the United States Patent and Trademark Office (F:         </div> <div style="border: 1px solid black; padding: 5px; margin-bottom: 5px;">           _____            (Date)         </div> <div style="border: 1px solid black; padding: 5px; margin-bottom: 5px;">           _____            Signature         </div> <div style="border: 1px solid black; padding: 5px;">           _____            Typed or Printed Name of Person Signing Certificate         </div> </div> <div style="width: 45%;"> <p style="text-align: center;"><b>Certificate of Mailing by First Class Mail</b></p> <div style="border: 1px solid black; padding: 5px; margin-bottom: 5px;">           I certify that this document and fee is being deposited on _____ with the U.S. Postal Service as first class mail under 37 C.F.R. 1.8 and is addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.         </div> <div style="border: 1px solid black; padding: 5px; margin-bottom: 5px;">           _____            Signature of Person Mailing Correspondence         </div> <div style="border: 1px solid black; padding: 5px;">           _____            Typed or Printed Name of Person Mailing Certificate         </div> </div> </div> <div style="margin-top: 10px;"> <p><b>*This certificate may only be used if paying by deposit account.</b></p> <div style="display: flex; justify-content: space-between; align-items: flex-end; margin-top: 10px;"> <div style="width: 45%;"> <div style="border-top: 1px solid black; width: 100%;"></div> <p style="text-align: center; font-size: small;">Signature</p> </div> <div style="width: 45%;"> <p>Dated: <i>May 6, 2004</i></p> </div> </div> </div>			

**Mara K. Featherstone**  
 Registration No. 50,390  
 STOEL RIVES LLP  
 One Utah Center  
 201 South Main Street, Suite 1100  
 Salt Lake City, Utah 84111  
 Tel: (801) 578-6992  
 Fax: (801) 578-6999

cc: